

**S/N10/650,207**

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	Aaron W. Janke et al.	Examiner:	George Evanisko
Serial No.:	10/650,207	Group Art Unit:	3762
Filed:	August 28, 2003	Docket No:	279.093US3
Title:	HIGH IMPEDANCE ELECTRODE TIP		

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**APPELLANTS' REPLY BRIEF UNDER 37 C.F.R. § 41.41**

MS Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

In response to the Examiner's Answer mailed September 10, 2007, please see the remarks below:

### **REMARKS**

Appellant has reviewed the Examiner's Answer, and believes the statements in the Appeal Brief remain accurate and compelling. In responding to the Answer, the Appellant would like to further explore a selected few of the points raised by the Office.

#### **§103 Rejection of the Claims**

Discussion of the rejection of claims 1-5, 7, and 8, under 35 U.S.C. 103(a) as being unpatentable over Bisping (US Pat. No. 4,886,074).

The Examiner's Answer cites a number of references which allegedly contain subject matter that the Examiner states would be obvious to combine the references with the Bisping reference.

Applicant traverses both the Examiner's interpretation of the prior art references and the motivation or suggestion to combine the references with the Bisping reference.

Regarding the Dutcher reference, on page 11 of the Examiner's Answer, the Examiner states that "Applicant's arguments amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references." The Examiner cites Dutcher for disclosing: a helix including non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient.

The Examiner's Answer asserts that "Dutcher shows in figures 5, 8, and 9, the plastic drug plug 138/238, covering/coating a portion of the outer surface of the helix, wherein the drug plug also contains an active ingredient." (Pages 11-12). The Examiner's Answer further states "[i]n addition, Dutcher shows the helix also contains another insulative coating, 133 or 233 (e.g. col. 3, line 57), that conforms to an outer surface of the helix and contains an active ingredient from drug plug 138, due to the migration of the drug from the plug or touching of the plug to insulative coating, 133 or 233." (Page 12).

Applicant submits that this is a mischaracterization of the cited reference. The Dutcher reference discusses a sheath 133 on a wire 131, and a drug plug 138. (Fig. 5, col. 4, lines 46-65). The drug plug 138 is a plug of material filling the interior of wire 131. Drug plug 138 cannot be

properly construed as a coating of non-soluble insulating material. Furthermore, even if a drug migrated onto sheath 133, it could not be construed that the sheath included an active ingredient. Accordingly, even if Dutcher were combined with Bisping, the combined structure does not read on the claimed: non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient.

Regarding the Altman reference, the Examiner's Answer states that "Altman states in column 15, lines 5-12 the use of non-soluble polymers as the insulative/non-conductive materials and discusses in column 10, lines 25-30 how a non-soluble insulative coating contains a drug similar to what is disclosed in US patent 5342628." (Page 12).

However, the polymer drug release device described in col. 10 of Altman is not explicitly described as non-soluble, and the discussion in column 15 is merely a laundry list of possible materials with no specificity of how they would be configured.

Thus, Appellant cannot find in Altman a helix including a non-soluble insulating material coated on at least a portion of its surface to conform to the outer surface of the helix, the insulating material including an active ingredient.

Moreover, Altman discusses different coatings for an implantable device which is for "effective elimination of an arrhythmogenic site." (Abstract). In contrast, Bisping relates to an implantable electrode type lead assembly. (Abstract). Thus, there appears to be no motivation to apply any of Altman's discussion to the lead of Bisping, since they are used for generally different purposes.

Moreover, Appellant believes the Office Action has provided insufficient motivation to modify the Bisping reference. Appellant notes that the mere fact that a reference can be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); MPEP § 2143.01.

On pages 12 and 13, the Examiner's Answer asserts that the combination would yield the predictable results of providing a biocompatible coating that does not degrade/breakdown in the body, to allow the electrical properties (impedance, current density, etc.) of the helix to be

changed for more effective sensing and pacing, the conforming coating to allow the fixation to be still inserted into the heart with out causing increased damage, and to include an active ingredient in the insulation to reduce irritability and inflammation of the helix.

However, the Examiner has not established that the Bisping reference needs such modifications or that one skilled in the art would be motivated to look for solutions to apparently non-existent problems.

Discussion of the rejection of claims 1, 2, 3, 7, and 8 under 35 U.S.C. 103(a) as being unpatentable over Grassi (US Pat. No. 4,624,265).

The Examiner's Answer cites a number of references which allegedly contain subject matter that the Examiner states would be obvious to combine the references with the Grassi reference. Applicant traverses both the Examiner's interpretation of the prior art references and the motivation or suggestion to combine the references with the Grassi reference, for the reasons given above for the Bisping reference.

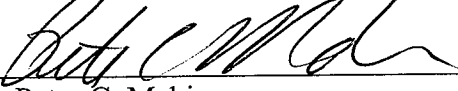
Conclusion

Appellant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Appellant's attorney at (612) 359-3267 to facilitate prosecution of this application.

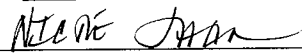
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Respectfully Submitted,

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**CERTIFICATE UNDER 37 CFR § 1.8:** The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Appeal Brief – Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 9 day of November 2007.

Name  Signature 